IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant: | Muthukumaran Natarajan et al. | Examiner: | Sun Jae Loewe |
| Serial No.: | 10/583,805 | Group Art Unit: | 1626 |
| Filed: | June 22, 2006 | Docket No.: | 2867.002US1 |
| Customer No.: | 21186 | Confirmation No.: | 4884 |

Title: NOVEL STABLE POLYMORPHIC FORMS OF AN ANTICONVULSANT

## DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. K. Srinivasu, declare and say as follows:

1. I am a citizen of India, and reside at Vadodara, Gujarat, India

2. I joined SUN PHARMACEUTICAL INDUSTRIES LIMITED ("SUN") on May 27, 1999 and have been working in their R&D centre, in the Organic Synthesis Department, ever since. At present, I hold the position of Senior Manager-R&D (Organic synthesis), heading a group of 9 scientists in Organic Chemistry. Over the past 10 years at SUN, I acquired proficiency in conducting Process Research and development of complex active pharmaceutical ingredients (API's) of interest to the organization

3. I pursued my academics in India and Graduated (1991) in Chemistry from Nagarjuna University, Andhra Pradesh; Post Graduated (1993) in Organic Chemistry from Kakatiya University, Andhra Pradesh; and was awarded my Ph.D. (Chemistry) in 2001 from Kakatiya University, Andhra Pradesh.

4. I have reviewed and understand the above-identified patent application, U.S. Serial No. 10/583,805, pending claims 1-4 thereof, the pending Office Action, and reference cited by the Examiner in the above-identified application. Specifically the reference is Gronvald et al. (U.S. Patent 5,010,090).

5. I am making the following statements as one of at least ordinary skill in the art in support of the patentability of pending claims 1-4 of U.S. Patent Application Serial No. 10/583,805.

6. In the Office Action mailed May 11, 2009, the Examiner rejected claims 1-4 under 35 U.S.C. § 102(b) as allegedly being anticipated by Gronvald et al. (U.S. Patent 5,010,090). The Office Action states "Applicant has not shown that the solid form produced in the reference is different from the form instantly claimed."

7. Under my direction, our laboratory studied the recrystallization of Tiagabine hydrochloride. Gronvald et al. does not disclose the details of their process for recrystallizing Tiagabine hydrochloride from ethyl acetate. Our laboratory recrystallized Tiagabine hydrochloride from ethyl acetate using recrystallization techniques well known to those skilled in the art for recrystallization of organic solids from organic solvents. The procedure described in the attached Exhibit I, involved heating Tiagabine hydrochloride in ethyl acetate at reflux, filtering the undissolved material, distilling off solvent, cooling, filtering, and washing with ethyl acetate.

8. As can be seen from the data presented in Exhibit I, Tiagabine hydrochloride has very poor solubility in ethyl acetate and dissolution of 2.0 grams of Tiagabine hydrochloride required more than 1,000 ml of ethyl acetate. In addition, as shown in Exhibit I, the Tiagabine hydrochloride obtained by recrystallization from ethyl acetate appeared light brown in colour with bluish tinge. The obtained material after recrystallisation by using large volume of ethyl acetate did not meet the basic requirement of appearance. Thus, our laboratory concluded that use of ethyl acetate as a recrystallization solvent was not feasible.

9. Further, to establish that the Tiagabine hydrochloride polymorph obtained by ethlyacetate recrystallisation is different from the Tiagabine hydrochloride polymorph IV recited in the claims of U.S. Patent Application Serial No. 10/583,805, we are enclosing two letters from Professor T. N. Guru Row of the Solid State and Structural Chemistry Unit, Indian Institute of Science, Bangalore India. Professor Guru Row analyzed the sample 7022/F/691/32A2 of Tiagabine hydrochloride prepared in our laboratory according to the procedure disclosed above and compared it with a sample of Tiagabine hydrochloride Polymorph IV prepared in our laboratory as disclosed and claimed in the present patent application, U.S. Patent Application Serial No. 10/583,805.

As can be seen from Professor Guru Row's letter, Exhibit II "Attempts to obtain a unique indexing on the pattern failed as we perceive that there is more than one phase associated with the sample or the sample is contaminated with impurity peaks."

As can be seen from Professor Guru Row's letter Exhibit III, "The XRD pattern of tiagabine HCl recrystallised from ethyl acetate is different from form IV of the US patent [US2007-0066656(AI)] and we conclude that the two materials are not the same."

This clearly indicates that the Tiagabine hydrochloride, obtained by recrystallization from ethyl acetate, is different from the new and previously unknown Tiagabine hydrochloride Polymorph IV claimed in U.S. Patent Application Serial No. 10/583,805.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and any patent issuing thereon.

Date: July 08, 2009.

K. Srinivasu

K. Srinivasu, Ph.D.